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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,413	04/06/2001	Robert H. DeBellis	59469/JPW/SHS/MVM	5162

7590 02/12/2004

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EXAMINER	
SAUCIER, SANDRA E	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/828,413	DEBELLIS ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *2-9,11 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,10 and 13-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 April 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-19 are pending. Claims 1, 10, 13-15, 17-19 considered on the merits. Claim 16 is drawn to a non-elected species, but is however, included in the prosecution.

This application contains claimd drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

Claims 1, 10, 13-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Insertion of the negative limitation "other than hydroxyurea" has no support in the as-filed specification. The insertion of this limitation is a new concept because it does not have literal support in the as-filed specification by way of generic disclosure, nor are there original claims with this negative proviso which would show possession of the concept of the exclusion of hydroxyurea. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter.

While applicants may argue that none of the examples show the use of hydroxyurea. However, the claims are not limited to the exemplified compounds. The concept which has been introduced is the **exclusion** of a specific antiviral compound in the practice of the claims while the composition **remains open** to all further antivirals. This is the new concept. Please see *Ex parte* Grasselli *et al.*.

In short, an inventor may carve out disclosed elements from his generic invention, that is he may claim less or fewer species, than the species which were **fully disclosed** as part of the invention, but he may not carve out elements which were not specifically disclosed as part of the original invention. The written description would not have conveyed to one having ordinary skill in the art that the applicant had possession of the concept now claimed, namely, the exclusion of the use of hydroxyurea with the inclusion of all other antivirals.

The exclusion of certain elements implies the permissible inclusion of all other elements not so expressly excluded. This clearly illustrates that such negative limitations do, in fact, introduce new concepts.

Claim Rejections - 35 USC § 102

Claims 1, 10, 17-19 are no longer rejected under 35 U.S.C. 102() as being clearly anticipated by Rodgers *et al.*. [IDS] or Ballas *et al.*. [IDS] in light of Lori *et al.*. [U] because of the inclusion of new matter.

Applicant is hereby notified that the insertion of new matter into the claims has necessitated the removal of the art rejection over claims above However, removal of new matter will result in the reinstatement of the art rejection.

Claims 1, 10, 13-15, 17-19 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by Lawson *et al.* [V].

The claims are directed to a one step method of treatment of a subject with sickle cell disease comprising administering an amount of an antiviral agent such as acyclovir effective to prevent sickling to treat the sickle cell disease.

The reference is relied upon as explained below.

Lawson *et al.* disclose administering acyclovir to a man with sickle cell trait. The oral dosage is 800 mg x 5. If the person weighed about 100 kg, this would be a dosage of about 400 mg/kg/day.

Because the patient is the same, namely a person afflicted with sickle cell disease, the compound administered is the same, acyclovir, and the amount administered falls within the ranges given in the specification on page 7 for an oral dosage as being an effective dose, the result of the treatment must necessarily, inherently be the same.

It is not relevant to the analysis of the claimed method that the reference makes no mention of (inhibiting, preventing etc.). Discovery of a new benefit for an old process does not render the old process patentable. In re Woodruff, 919 F. 2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). Merely because the reference did not have one of applicant's purposes in mind when the (drug was administered) does not alter the drug's physiological activity. In the context of an anticipation rejection, the Federal Circuit stated, "Where, as here, the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results." Mehl/Biophile Int'l Corp. v. Milgraum, 192 F. 3d 1362, 1366, 52 USPQ2d 1303, 1307 (Fed. Cir. 1999).

See also *In re* Cruciferous Sprout 64 USPQ2d 1202 Fed. Circuit, where the Federal Circuit upheld a decision that patents licensed to Brassica Protection Products, Inc. are invalid because they are anticipated by the prior art. The patents are for method of growing and eating certain sprouts to reduce the level of carcinogens in animals, thereby reducing the risk of developing cancer. Prior art references disclose growing and eating those specific sprouts. The Federal Circuit cited authority for the rule that "a prior art reference may anticipate when the claim limitations not expressly found in the that reference are nonetheless inherent in it." The court said, "While Brassica may have

recognized something quite interesting about (eating) those sprouts, it simply has not invented anything new.".

Response to Arguments

Applicant's arguments filed 11/17/03 have been fully considered but they are not persuasive.

Applicants argue that Lawson et al. describe the administration of acyclovir in order to treat herpes simplex ½ or varicella zoster and that the doctors were not prompted to administer acyclovir to treat the patient's sickle cell disease. Therefore, the acyclovir was not administered to treat the patient's sickle cell disease, that is to prevent the sickling of erythrocytes.

Since the patient is the same in the prior art and in the claimed method (a patient with sickle cell disease), the one step method of administering acyclovir is the same in the prior art and in the claimed method, the mode of administration and amount administered is the same in the prior art disclosure and in the claimed method, the result (prevention of the sickling of erythrocytes) would reasonably be assumed to be the same also. This is an argument of inherency which applicants have not persuasively rebutted.

See also Ex parte Novitski, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) The board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of P. cepacia. A US patent to Dart disclosed inoculation using P. cepacia bacteria for protecting the plant from fungal disease. Dart was silent with regard to nematode inhibition, but the Board concluded that nematode inhibition was an inherent property of the bacteria, and therefore of the method as disclosed by Dart.

If Applicants would direct their attention to distinguishing their claimed method from the prior art by the use of distinct compound, a

distinct mode of administration or a distinct amount of the drug to be administered, prosecution might be advanced.

Allowable Subject Matter

Claim 16 is directed to allowable subject matter.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) -272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor is M. Wityshyn. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sandra Saucier
Primary Examiner
Art Unit 1651